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for Corn Dry Mills

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### **FULL REPORT**

Archive(original)  
J. Dykes (Agredoc)  
D. Bushey  
R. Jones  
I. Kelly  
M. McAuley  
S. MacIntosh  
L. Powell  
R. Shillito  
L.Somerville

### **SUMMARY ONLY**

L. Somerville  
P. Cherny  
B. Henry  
J. Wichtrich  
M. Gadsby

Date Distributed: 4/12/01

**B003273**Title**The Aventis CropScience StarLink™ Quality ✓ Plan for Corn Dry Mills**Author(s)**Dean Bushey  
Iain Kelly  
Mark McAuley**Test Guideline**Not Applicable**Completed On**12 April 2001**Sponsor**Aventis CropScience  
PO Box 12014, Research Triangle Park, NC 27709  
USA**Testing Facility**Aventis CropScience  
PO Box 12014, Research Triangle Park, NC 27709  
USA**Study Identification**B003273**



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## **STATEMENT OF NO DATA CONFIDENTIALITY CLAIMS**

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Company                      Aventis CropScience USA LP  
                                    2 T.W. Alexander Drive  
                                    Research Triangle Park, NC 27709

Company Agent            *Luann Powell*  
                                    Luann Powell  
                                    Registration Manager-Biotechnology

*13 Apr 01*  
Date

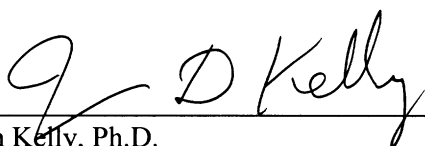

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**GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT**


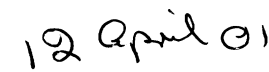
The study presented herein is not subject to the 40 CFR 160 Good Laboratory Practice Standards.

It does not contain original scientific data.


Author:

  
\_\_\_\_\_  
Iain Kelly, Ph.D.  
Manager, Risk Assessment  
\_\_\_\_\_  
Date

Sponsor

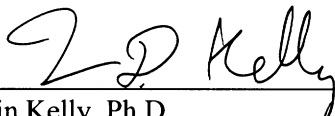
  
\_\_\_\_\_  
Larry Somerville, Ph.D.  
Director, Scientific Affairs  
\_\_\_\_\_  
Date

Submitter

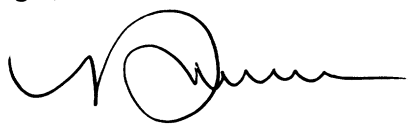
  
\_\_\_\_\_  
Luann Powell  
Registration, Manager-Biotechnology  
\_\_\_\_\_  
Date

**APPROVALS PAGE**

Study Director/Author

  
\_\_\_\_\_  
Iain Kelly, Ph.D.  
Manager, Risk Assessment12 Apr 01  
Date

Department Head

  
\_\_\_\_\_  
Larry Somerville, Ph.D.  
Director, Scientific Affairs12 April 01  
Date

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## **The Aventis CropScience StarLink™ Quality √ Plan for Corn Dry Mills**

### **1. OBJECTIVE OF PROGRAM**

The Aventis CropScience StarLink Quality √ Plan for corn dry mills has been developed to restrict the movement of Cry9C protein into foods produced from dry milled corn. Aventis has developed this program based on a review of the corn dry milling industry in the U.S. The program is comprised of three components:

1. Testing of containers arriving at the mill (front-end testing)
2. An Aventis controlled quality assurance/auditing program
3. A documented training program for testing personnel

This document lays out the rationale behind the program as well as giving full details of the plan (Appendix 1). Aventis believes that, if a mill participates in the program, it will be undertaking reasonable steps to ensure that there will be virtually no Cry9C protein in food products produced from its dry-milled corn.

The data from mills participating in this program will be maintained in a secure Internet application where authorized ACS and FDA personnel will have access to summary results from the front end testing. Recording the results in this manner will insure that the required testing is taking place and will allow the continued monitoring of Cry9C arriving at the mills to support the eventual elimination of this program at some point in the future.

### **2. DRY MILLING OVERVIEW**

The objective of the dry milling process is to remove the bran coat and germ from the corn kernel while keeping the endosperm portion largely intact. This process yields “prime products” which are high in starch, low in oil, essentially free of bran and germ, and which have excellent shelf-life and stability. These “prime products” range from flaking grits to corn flour (as well as refined corn bran) along with co-products corn oil and hominy feed. Prime products are used in the production of a wide variety of food and beverage applications, including: breakfast cereals, malt beverages, snack foods, prepared mixes, batter mixes, and low calorie/high fiber foods.

A sub-set of dry milling is the production of Masa dough which undergoes chemical treatment prior to milling. Masa dough is alkaline-cooked corn, which is used in tortillas, tortilla chips, corn chips and other similar items. Whole kernel corn is cooked in near-boiling water containing 1% lime for approximately 20 minutes. The corn is allowed to soak for 8-12 hours (steeping). The corn is then drained from the steep water and washed with clean water to remove excess lime and the pericarp, which has been loosened. The washed corn is now at about 45-50% moisture and is subjected to stone grinding to form a dough. If the dough is formed into strips and fried, corn chips are produced. If the dough is formed into thin pancake-like sheets and baked, corn tortillas are produced. If the baked tortillas are subsequently fried, tortilla chips are produced.

Figure 1 outlines the source of corn reaching dry mills in the U.S. Dry mills utilize only about 2% of the corn grown annually, representing approximately 161 million bushel, this includes 50-60 million

bushel used in the brewing process. There is an additional 55 million bushels used to prepare Masa dough. This compares to 1 billion bushels of corn processed annually by wet milling. The North American Millers Association (NAMA) lists 51 corn dry mills (See Figure 3). Approximately 12 of these mills handle in the region of 90% of the dry milled corn.

Corn dry milling is a relatively small, well-contained industry. Controlling the movement of Cry9C protein into food products is, therefore, very similar in scope to that of limiting aflatoxins in food from peanuts. Like aflatoxin control, it is a manageable proposition if corn moving into dry mills can be tested and confirmed to have Cry9C at levels below 20 ppb. This level will ensure that the protein found in finished food products is minimum or below detectable amounts.

### **3. TYPICAL MILLING OPERATIONS**

Most deliveries to dry mill operations arrive in 900-bushel trucks. Occasionally a rail car, barge or smaller truck is received. A mill may be handling up to 200 trucks per day and at peak periods this can rise to 600. To control corn at the point of receipt, testing for Cry9C must be rapid, simple and reliable.

Prior to processing, received corn is unloaded into storage silos. A typical storage silo may hold 50,000 bushels.

Corn is then typically processed by the following procedures:

1. Cleaning. Broken corn and foreign material removed
2. Tempering. The moisture content of corn is raised to about 20%.
3. Degermination. Bran coat and germ separated from the endosperm in an attrition mill
4. Aspiration. Additional bran and light germ pieces aspirated from the endosperm
5. Milling and sifting. Additional germ particles removed. Endosperm pieces sized to the desired granulation.
6. Drying and cooling. Moisture content reduced to the desired ranges for finished product.

#### 4. TESTING PROCEDURES

Several testing methods for the Cry9C protein or for the DNA that is translated into Cry9C protein are available as shown below:

##### Methods Comparison for Cry9C Detection

Testing Method	Comments
Lateral Flow Strip	Rapid Easy and reliable, Less sensitive than ELISA Defines maximum amount in sample
ELISA	Slow Accurate and quantitative. Moderately easy to perform but requires specialist equipment.
PCR	Slow Difficult to perform quantitatively. Does not indicate presence of protein, only DNA Susceptible to false positives

#### 5. BRIEF DESCRIPTION OF METHODS

##### 5.1 Lateral Flow Strip

The lateral flow strip test provides a very simple, rapid test for Cry9C protein that does not require any specialist equipment other than the strips themselves. Milled corn or corn products are shaken with water. The lateral flow strip is then placed in a small amount of the water extract and developed for ten minutes. Two red bands appear if Cry9C protein is present and one if it is not.

The assay uses a double antibody sandwich format. Antibodies specific to the Cry9C protein are coupled to a color reagent and incorporated into the lateral flow strip. When the lateral flow strip is placed in a small amount of an extract from plant tissue that contains Cry9C protein, binding occurs between the coupled antibody and the protein. A sandwich is formed with some, but not all the antibody that is coupled to the color reagent. The membrane contains two capture zones, one captures the bound Cry9C protein and the other captures the color reagent. These capture zones display a reddish color when the sandwich and/or unreacted colored reagents are captured in the specific zones on the membrane. The presence of only one line (control line) on the membrane indicates a negative sample and the presence of two lines indicates a positive sample.

Lateral flow test strips provide a yes/no answer for the presence or absence of Cry9C protein in a given sample. Testing multiple, statistically selected sub-samples allows an estimate of the

percent of Cry9C corn. The test results provide information about the probability of the presence of Cry9C corn in the sample.

The statistical model for this application is based on the Poisson Probability Distribution, which provides good approximations to binomial (yes/no) probabilities when the number of items tested (i.e. corn kernels) is large but the probability of a positive result is expected to be small (i.e. low percentage of Cry9C corn).

The following tables provide information at the 95<sup>th</sup> confidence levels with the use of 800 kernels per sub-sample. The limit of sensitivity of the test is one positive kernel in 800. The table lists the maximum percent of StarLink kernels that can be expected in the sample if all test-samples provide negative results.

No. Sub-Samples of 800 Seeds Each	Percent StarLink (95 <sup>th</sup> CI)
<b>1</b>	0.375
<b>2</b>	0.187
<b>3</b>	0.125
<b>4</b>	0.094

If three samples are tested it can be assumed that trucks accepted into a mill have a 95% certainty of having less than 0.125% StarLink kernels. As the average Cry9C concentration of StarLink corn is 15 ppm, this equates to 20 ppb or less Cry9C in the corn.

## 5.2 ELISA

The principle of the Enzyme-Linked ImmunoSorbent Assay (ELISA) is very similar to the strip test but is designed for quantitative laboratory detection of Cry9C protein. It is a sandwich enzyme-linked technique.

In the test, extracts of ground corn or corn products are added to test wells coated with antibodies raised against Cry9C protein. Any Cry9C present in the sample extract bind to the antibodies, and is then detected by addition of enzyme (horseradish peroxidase)-labeled Cry9C antibody. After a simple wash step, the results of the assay are visualized with a color development step. Color development is proportional to the Cry9C concentration in the sample extract. The Cry9C can be quantified against a set of known standards using a spectrophotometer to measure color intensity. More intense color indicates a higher concentration of Cry9C.

The Limit of Detection (LOD) of the ELISA test, as stated in the manufacturer's literature, is 0.35 ppb. Typically the concentration at which Cry9C protein can be reliably measured is 3 times the LOD. This sets the Limit of Quantification (LOQ) at 1 ppb. The detection limit of the kit is lower, but utilizing values below the LOQ increases the probability of false positives.

### 5.3 PCR

Polymerase chain reaction (PCR) does not measure the presence of Cry9C protein. It measures the presence of a fragment of the DNA which produces the Cry9C protein. It is a technique that is used to amplify the number of copies of a specific region of DNA, in order to produce enough DNA to be detected.

PCR allows a short stretch of DNA (usually fewer than 3000 base pairs) to be amplified to about a million fold by running multiple cycles of denaturation, annealing and DNA synthesis. The particular stretch of DNA to be amplified, called the target sequence, is identified by a specific pair of DNA primers. These are oligonucleotides, usually about 20 nucleotides in length. Different testing laboratories use different primers and are therefore amplifying different fragments of the DNA sequence. The DNA formed is chromatographed in a gel to identify it as a *cry9c* gene fragment.

Because of the million-fold magnification step the PCR technique is sensitive to cross contamination and false positives can result if precautionary steps are not taken. Mills involved in the testing of corn for the presence of StarLink have experienced such problems when attempting to use PCR as the preferred analytical method. In an attempt to gain the best possible data, the mills frequently have sent split samples to different laboratories. Unfortunately, correlation of positive findings has been somewhat erratic between the paired laboratories with as little as 33% agreement noted on occasions. In one extreme case a mill reported sending 26 samples that were positive in one laboratory to two additional laboratories. All 26 samples tested negative at these two latter facilities.

Due to the variability across laboratories, the PCR tests for *cry9c* DNA needs more investigation to increase confidence in the results. Regardless, as it is an indirect test for the possible presence of Cry9C protein, the relevance of the PCR results is of questionable utility.

## 6. DILUTION OF CRY 9C DURING MILLING AND PROCESSING

The concentration of Cry9C in final food products will be reduced significantly during the milling and food processing operations.

### 6.1 Effect of Mill Operations on the Cry9C Concentration

After truckloads of corn are accepted into a mill there will be considerable mixing of the corn through all the mechanical steps outlined in Section 3. If the distribution of concentrations in accepted trucks was known (i.e. trucks containing less than 0.125% Cry9C) the concentration in finished product could be determined based on the amount of mixing estimated to be occurring. From the number of rejects from mills that Aventis have contacted, estimates indicate that generally less than 5% of trucks arriving at mills contain greater than 0.125% Cry9C corn kernels. This low level of rejection would tend to indicate that the concentration in accepted trucks is well below the 0.125% limit.

If the actual concentration of Cry9C was known in only rejected trucks, statistical models are available which would allow the distribution of Cry9C in accepted trucks to be determined. As outlined below, however, Aventis considers that sufficient information will be available from the Quality √ Plan to render this information unnecessary.

Four different scenarios for Cry9C concentrations in trucks being accepted by mills were considered:

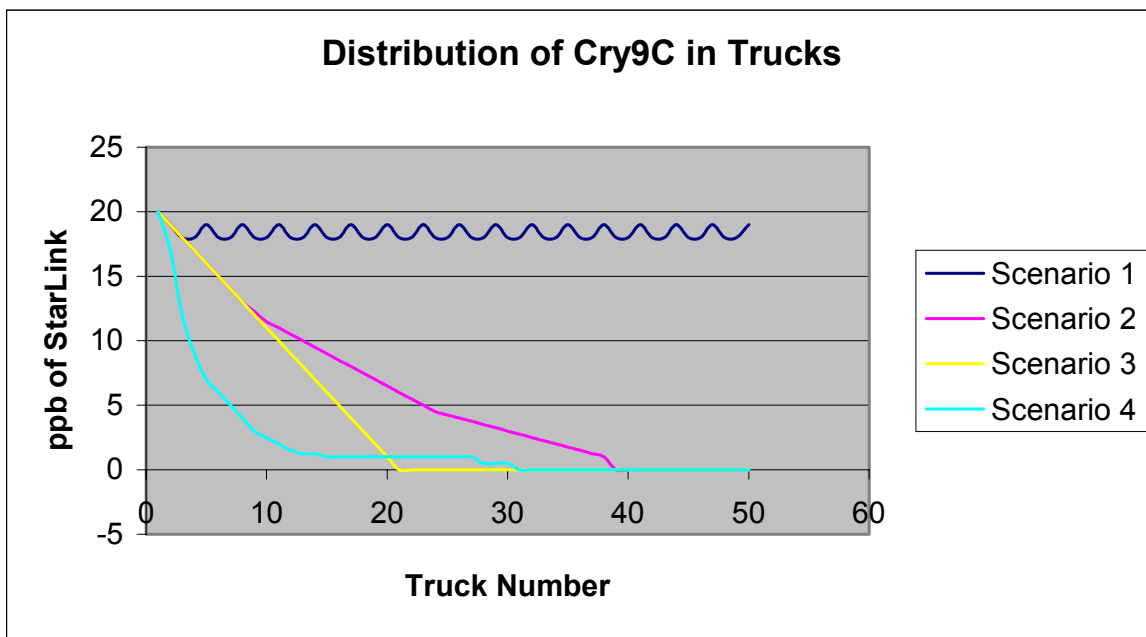
Scenario 1: All fifty trucks have a level of Cry9C just below the detection limit of the strip assay, i.e. 18-19 ppb level. This is an unrealistic “worst case” for the distribution when present indications are that less than 5% of trucks arriving at mills contain greater than 0.125%.

Scenario 2: There is a linear relationship in the amount of Cry9C present per truck. Only 13 trucks are Cry9C free. Half of the trucks have more than 8 ppb of Cry9C.

Scenario 3: There is a steeper linear relationship of Cry9C per truck than in Scenario 2. Thirty of the 50 trucks are below the 1 ppb level.

Scenario 4: The level of Cry9C declines exponentially and levels off at very low rates. Twenty trucks are Cry9C free but 19 more are below 2 ppb. This is the “best case” of the scenarios described here.

These scenarios are depicted graphically below:



The following assumptions were made in calculating concentrations of Cry9C in finished milled products:

The strip test used as the front-end test is effective at screening Cry9C out of the system at a level above 20 ppb (0.125% StarLink corn). Once the corn has been accepted into the mill, 50 truckloads are combined in a single bin. Processing steps results in complete mixing of the Cry9C from the 50 Trucks.

Based on these assumptions the concentration of Cry9C in the storage bins would be:

	Scenario #1	Scenario #2	Scenario #3	Scenario #4
Conc. of Cry9C (ppb) in meal or flour	18.4	6.0	4.2	2.1

## 6.2 Effects of Processing on Cry9C Concentration

Aventis CropScience has looked at the effect of food processing on the amount of Cry9C that is in any given food after processing (1). Although a wide range of products are produced they can be divided into two broad categories: highly processed food products and cooked/baked food products (minimally processed). This is illustrated in Figure 2 and tabulated below.

Category	Typical Representative Foods	Cry9C in processed Foods (% of original)
Processed Food Products (highly processed)	Taco Shells Masa dough Extruded Snack Foods Extruded Cereals Corn Flakes	Non-detectable – 0.89
Cooked/Baked Food Product (minimally processed)	Corn Bread Bread Coatings Batters Corn Dogs	3.4 – 18.4

For minimally processed foods, with the exception of flour and corn meal which is processed by the consumer, the highest percentage remaining is 18.4% in hush puppies, a reduction by a factor of 5.7. For highly processed foods, the highest percentage remaining is 0.89% in Masa dough, a reduction by a factor of 112. Using this information one can then calculate the maximum level of Cry9C anticipated in processed foods in the four scenarios above by dividing by the reduction factors.

	Scenario #1	Scenario #2	Scenario #3	Scenario #4
Max. conc. of Cry9C (ppb) in highly processed foods	0.16	0.05	0.04	0.02
Max. conc. of Cry9C (ppb) in minimally processed foods	3.4	1.1	0.7	0.4

Only under Scenario 1 and 2 does the level of Cry9C clearly exceed the Limit of Quantification of the most sensitive protein test available (ELISA), and then only for minimally processed foods. As discussed above, Scenario 1 is beyond a realistic worst case scenario based on the low percentage of rejects mills are presently experiencing. Scenario 2 is right at the Level of Quantification at 1.0 ppb. It should be noted that the manufacture's of the ELISA test claim a Level of Detection at 0.35 ppb.

## 7. CONCLUSIONS

Corn dry milling in the U.S. is a relatively small, well-contained industry. Controlling the movement of Cry9C protein into mills is therefore a manageable proposition, very similar in scope to that of limiting aflatoxins in food from peanuts.

Testing of incoming shipments of grain to all mills is feasible. Three samples of 800 kernels can be tested in approximately 15 minutes and provides a 95% certainty that the level of Cry9C protein is less than 20 ppb.

Using reasonable assumptions of mixing during storage, milling and processing, coupled with measured processing factors, residues in finished foods (excluding corn meal and flour which is processed by the consumer) are highly likely to be at or below the limit of quantification of the most sensitive protein test available (ELISA).

Aventis is advocating the introduction of the Quality  $\sqrt{}$  Plan (See Appendix I) to insure that front end testing is performed at all mills in a reliable and consistent manner. Entering the results on the Quality  $\sqrt{}$  Plan Internet site will provide an immediate and up-to-date view of the percentage of corn being delivered to the dry mills and testing negative for the presence of Cry9C.

## 8. REFERENCES

- 1) Detection of Cry9C protein in dry milled, wet milled and masa processed fractions and processed foods mad from 100% StarLink grain.  
R.D. Shillito, S. MacIntosh and W.J. Kowite. (2001). Aventis CropScience Report CM00B014

Figure 1. Distribution Profile of The U.S. Corn Harvest

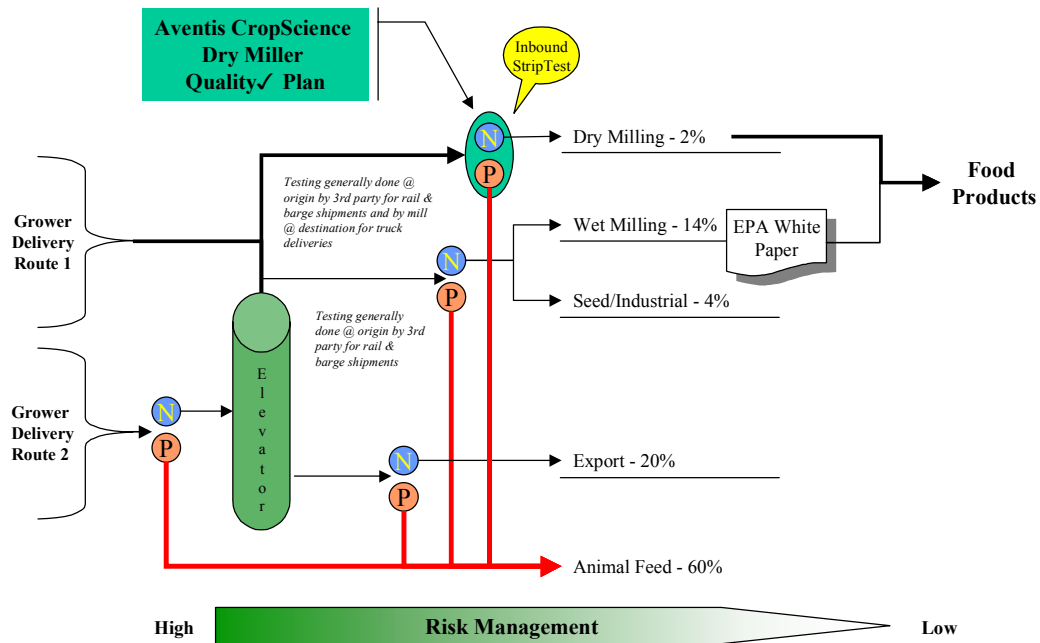


Figure 2. Quality Plan will require controlled testing of all inbound corn shipments

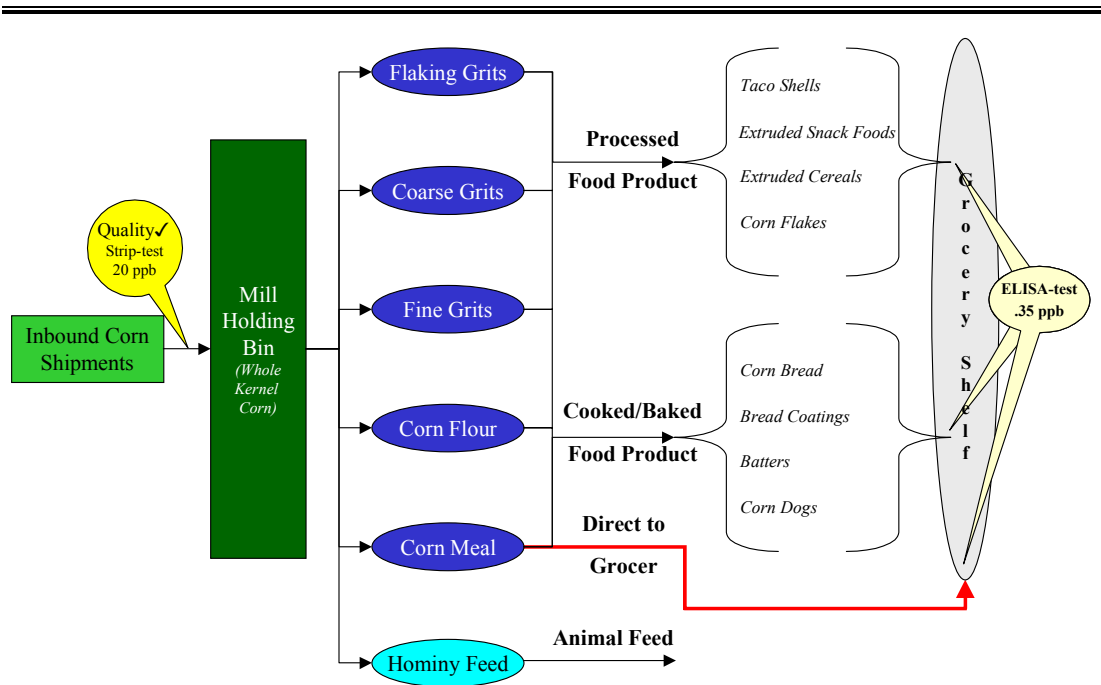
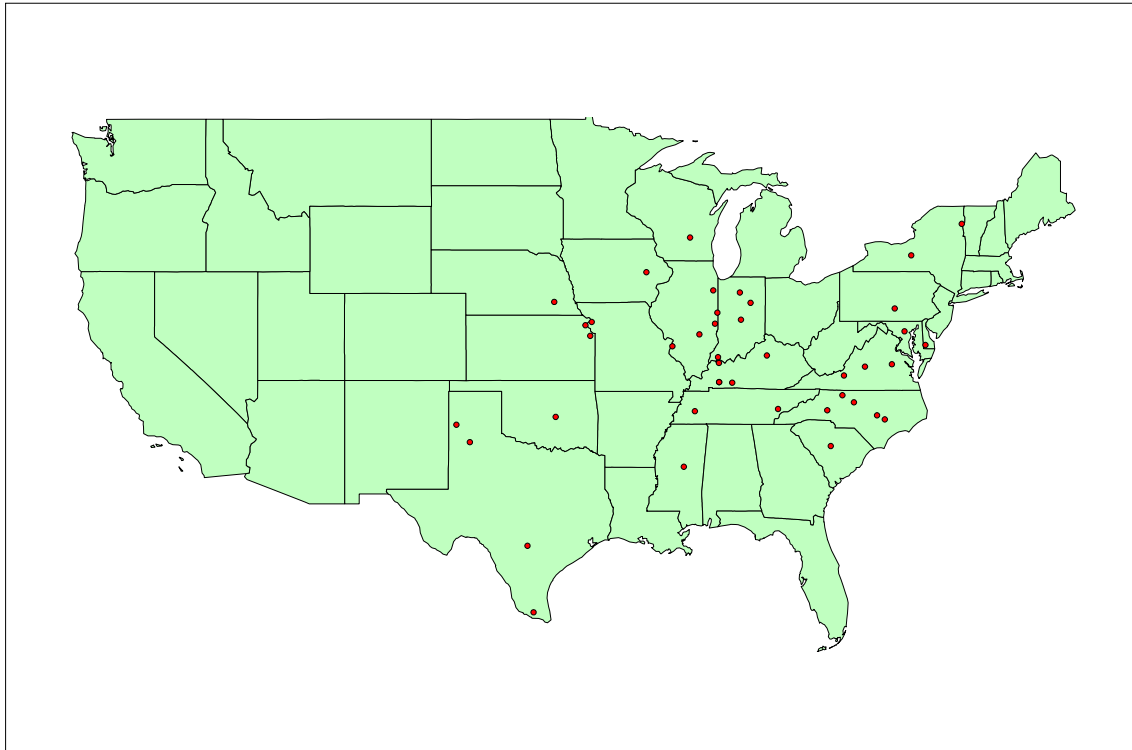


Figure 3      Dry Mills in the US



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Appendix 1      Protocols For The Aventis CropScience StarLink Quality √ Plan For Corn Dry Mills

## OVERVIEW

The purpose of this document is to lay out, in detail, the components of the Aventis CropScience Quality √ Plan for dry mills. Protocols for the following three components of the Quality √ Plan are outlined in this Appendix:

- 1) Testing of containers arriving at the mill (front-end testing)
- 2) An Aventis controlled quality assurance/auditing program
- 3) A documented training program for testing personnel

Each component must be followed.

## 1. FRONT-END TESTING

## 1.1      Purpose

To assure no corn, testing positive for StarLink, is accepted by the mill.

## 1.2      Sampling of Containers

- 1) Each container (truck, rail, or barge) arriving at the mill must be sampled multiple times according to the accepted USDA GIPSA sampling method for the container type. Additionally at least one sample must be taken from a random location within the container. This will assure that a representative sample is obtained. All incoming containers must be sampled and tested at the mill regardless of whether a 'StarLink Free' certificate accompanies the shipment, as may be the case with railcar and barges.
- 2) All of the above samples from a single container are thoroughly mixed together to give one homogeneous batch. This sample may be split for use in other testing procedures. One half of this sample is maintained for StarLink testing.

## 1.3      Ordering of Test Kits

All samples will be tested for the Cry9C protein using Aventis approved StarLink lateral flow strips. These should be ordered by contacting:

Sue Kincaid  
Aventis CropScience  
2 T.W. Alexander Drive  
Research Triangle Park, NC 27709  
Phone # 919-549-2073

Instructions will also be posted on the internet at:  
<http://www.starlink.com> under the Quality √ Plan

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#### 1.4 Testing for Cry9C

- 1) Triplicate sub-samples from each sample in Section 2.2 (2) will be tested using Aventis approved StarLink lateral flow strips.
- 2) Tests should be run in accordance with the manufacture's instructions, but to ensure consistency in the program the criteria laid out below must be followed.
- 3) Weigh out 3 separate sub-samples of 800 kernels for grinding. Note that it is important to grind three samples separately. Grinding one large sample then sub-sampling reduces the sensitivity of the test.
- 4) In order to prevent cross contamination make sure the grinder is clean from the previous set of 3 sub-samples before placing the kernels in the grinder. If the previous sample was positive or if you do not yet have a result and the grinder is not of the type that can be washed and rinsed then run at least 250 grams of StarLink negative corn through the mill before the next test sample.
- 5) Grind each sample separately to a particle size equivalent to, or smaller than, brewers grit.
- 6) Place each sample in a separate container.
- 7) Add 300 ml of water to each sample container.
- 8) Mix thoroughly for 30 seconds.
- 9) Allow container to sit for 1 min and transfer 0.5 ml (500 µl) of supernatant (using the disposable pipette supplied with the kit) into the reaction tube.
- 10) Add Aventis approved StarLink lateral flow strip.
- 11) Wait 10 minutes before removing the strip.
- 12) Label the strip and inspect the test strip for appropriate control bands and positive StarLink bands.
- 13) All strips should show a positive control band. If this is not present run another strip on the same sample
- 14) If any of the 3 strips show positive for StarLink at any level of intensity the load is rejected.

## 1.5 Recording of Results

Record the results in a notebook or on a datasheet identifying:

- 1) A unique container identifier (e.g. truck number and time)
- 2) Date
- 3) Analyst
- 4) Number of positive strips
- 5) Attach the dried strips to the notebook, or datasheet. This is best accomplished by cutting off the ends the strip and retaining the center portion.
- 6) Maintain the results in a safe location pending QA audit.

## 1.6 Validation of Testing Procedures

Aventis will supply a pre-milled positive StarLink test sample spiked at the rate of 1 kernel of StarLink in 800 kernels. Contact Bill Kowite (919-549-2511) at ACS for sample.

Once a day, or every 50 samples, whichever is less, each mill must run the following test:

- 1) For each test weigh out 2 g of the above sample
- 2) Add 4 ml of water.
- 3) Mix thoroughly for 30 seconds
- 4) Allow container to sit for 1 min and remove 0.5 ml (500  $\mu$ l) of supernatant, using the disposable pipette supplied with the kit, and place in the reaction tube.
- 5) Add Aventis approved StarLink lateral flow strip.
- 6) Allow 10 minutes and remove the strip.
- 7) Label the strip and inspect the test strip for both a control band and positive StarLink band. If these are not present contact your supervisor who may contact Aventis (Dr. Ray Shillito – 919-549-2210) if the problem cannot be solved locally.
- 8) Label all tests and attach the dried strips to the notebook or datasheet recording the date, time and performing analyst.
- 9) Maintain the results in a safe location pending QA audit.

## 2. QUALITY ASSURANCE/AUDITING PROGRAM

### 2.1 Purpose

To allow ACS to guarantee that the protocol outlined in the program is being followed.

### 2.2 Program Components

- 1) ACS will do spot checks at the facilities to determine whether the protocols are being followed, inspect records, and collect random grab samples. Each mill will be visited based on a schedule that minimizes the number of samples that need to be maintained on site.
- 2) ACS may send out samples to the mill that are known to contain or not contain StarLink at detectable levels and have the mill run these samples and report the result.

- 
- 3) ACS maintains the right to request retains of samples that were determined to be positive by the strip test. These samples (1 kg) will be sent to RTP for validation and testing.
  - 4) All Test results (including all inbound corn shipments and samples sent to the dry mill by ACS) must also be entered on the Quality √ Plan web site. The data entry site can be found at <http://www.starlink.com> under the Quality √ Plan
  - 5) ACS can make the data available to FDA should they request it.

### 3. TRAINING PROGRAM

#### 3.1 Purpose

The guarantee that all participants in the program are sampling, testing, and reporting in a consistent and accurate manner.

#### 3.2 Components of the Program

- 1) A training guide will be made freely available to all participants in the program. This will be in the form of paper documentation plus a multi-media presentation.
- 2) Positive samples of StarLink corn, which have been confirmed by ACS, will be supplied to each mill for the required positive controls.
- 3) All analysts must have a documented training record held at the mill, which shows they have reviewed the Aventis training material and successfully run the test. Records must be signed and dated by the analyst and the supervisor.
- 4) A signed statement from each mill will be required where they acknowledge their understanding of the protocol and their willingness to comply with this protocol approved by ACS. ACS will issue a certificate to the mill to document their acceptance into the program.
- 5) If requested by the mill, ACS will supply hands on training for the analyst.
- 6) Participants will have the opportunity to discuss details of the program with Aventis as minor deviations may be required in specific mill settings.